2. The method according to claim 1 wherein the antibody or antigen to anti-HIV is [can be] selected from the group consisting of anti-HIV (I or II), anti-anti-HIV, HIV antigens (I or II), recombinant HIV antigens, HIV aptamers, anti-Human IgG, IgA, IgD, IgE, or IgM.

3. The method according to claim 1 in which the buffer is [can] selected from the [following] group consisting of citrate, hepes, tris (trizma), taps, popso, tes, pipes, mopso, tricine, mops, mes, bicine, bes, caps, epps, dipso, ches, capso, ampso, aces, ada, bis-tris-propane, tapso, heppso, tea, amp, phosphate, phthalate, succinate, hydrochloric acid, sulfuric acid, nitric acid, acetic acid, sodium hydroxide, and potassium hydroxide.

4. The method according to claim 1 wherein the test sample is [can be] any biological fluid selected from the following group: urine, serum, whole blood, saliva, cerebral spinal fluid, gastric contents, and extracts of hair or sweat.

9. The method according to claim [1] 6 for determining the anti-HIV concentration of a test sample wherein the sample can be normalized comprising the steps of dividing the anti-HIV concentration by creatinine, cystatin C, or specific gravity concentration [can be used to normalize the sample for accurate determination of anti-HIV].

10. The method according to claim [9] 7 [wherein the calculation to normalize] for determining the anti-HIV concentration of a test sample wherein the sample can be normalized comprising the steps of [requires that it be] divid[ed]ing the anti-HIV concentration by the creatinine, cystatin C, or specific gravity concentration [of the same

test sample thereby yielding the anti-HIV to creatinine, cystatin C, or specific gravity ratio].

Comments on claims 9 and 10 in Response to the Examiner questions:

As described in detail and length in the specification pages 27, 28, and 34-36 the novel use of "creatinine or cystatin C excreted by a normal, healthy individual is relatively consistent from day to day", page 28, 1st paragraph of the specification. As known in the art and as stated in 'Tietz Textbook of Clinical Chemistry, 2nd Edition", 1994, W.B Saunders, page 1533, 2nd paragraph, "Because creatinine is endogenously produced and released into body fluids at a **constant rate** and its plasma levels maintained within narrow limits, its clearance may be measured as an indicator of GFR." (GFR, stands for glomerular filtration rate), therefore, the use of creatinine or other steady state markers are valid for consistent day to day measurement of urine concentration.

Specific gravity concentration is "A useful guide to the adequacy of the renal concentrating mechanism is measurement of urine specific gravity" as stated in the above reference page 1556, 3rd paragraph.

The Examiner asks:

a) What is the sample "normalized" to? Answer: The samples anti-HIV value is normalized to a specific value by dividing the anti-HIV value by the creatinine, cystatin, or specific gravity concentration of the test sample. See pages 35 and 36 of the specification for more detail.

b) Is there a specific concentration necessary for the samples before employing the test method? Answer: No. See pages 35 and 36 of the specification for more detail.

c) Is it possible to use these reagents or not? Answer: The term "reagents" not used in claim 9 or 10.

REMARKS - General